

Program Announcements (PA'S)

MOLECULAR AND STRUCTURAL BIOLOGY OF HAIR AND ITS DISEASES WITH SPECIAL REFERENCE TO ALOPECIA AREATA

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE

The Skin Diseases Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), supports research on the structure, function, and diseases of the skin and its appendages. This program announcement is issued to encourage submission of research and fellowship grant applications in the area of molecular and structural biology of hair and its diseases with special reference to alopecia areata.

BACKGROUND

The hair follicle is a complex three-dimensionally organized skin appendage that cycles through stages of involution and regeneration over time. It is subject to hormonal influences and genetic effects as well as regional variation with body site. It is also subject to many diseases, both hereditary and acquired. The most common and often the most debilitating among the acquired diseases is alopecia areata. This condition has been thought to be a manifestation of a tissue-specific autoimmune disease, but definitive proof is still lacking.

The current state of knowledge of the molecular and structural biology of hair and the state of research in alopecia areata was summarized at two recent conferences cosponsored by NIAMS. These conferences emphasized the new knowledge being acquired in these areas of hair research but, more importantly, pointed out the many areas in which additional research is necessary to obtain a clear understanding of normal and abnormal processes and disease states.

RESEARCH GOALS AND SCOPE

The goal of this program announcement is to stimulate research in these areas of hair biology and disease. Some of the research objectives appropriate for inclusion in applications responsive to this program announcement are:

- o Studies of molecular and structural biology of normal hair during its normal cycle;
- o Hereditary diseases of hair to elucidate the underlying defect and the mechanism by which the disease state is expressed;
- o Hormonal influences on normal and diseased hair;
- o Etiopathogenesis and treatment of acquired hair diseases, particularly alopecia areata;

- o Epidemiologic studies of diseases of hair.

MECHANISM OF SUPPORT

Research mechanisms to support these investigations include research grants (RO1), Clinical Investigator Awards (KO8), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Service Awards (F32).

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the

relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research and fellowship grants. Review criteria include significance and originality of the research goals and approaches; feasibility of the research and adequacy of the experimental design; training, research competence, and dedication of the investigator(s); adequacy of available facilities; and provision for the humane care of animals. Decisions will be based on initial review group and National Advisory Council recommendations.

Applications must be submitted on form PHS 398 (rev. 10/88), for research grant awards or on form PHS 416-1 (rev. 4/89) for fellowship awards. available in the business or grants office at most academic or research institutions, and from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, Maryland 20892, telephone (301) 496-7441.

Applications will be accepted in accordance with the submission dates for new applications on a continuing basis:

February 1, June 1, October 1 for research grant applications. January 10, May 10, September 10 for fellowship applications.

The phrase, "MOLECULAR AND STRUCTURAL BIOLOGY OF HAIR AND ITS DISEASES WITH SPECIAL REFERENCE TO ALOPECIA AREATA, PA-91-59" must be typed on line 2 of the face page of the application. The original and six copies of the PHS 398 or the original and two copies of the PHS 416-1 must be sent or delivered to:

Grant Application Receipt Office
Division of Research Grants
Westwood Building, Room 240
National Institutes of Health
Bethesda, MD 20892-4500**

For further information, investigators are encouraged to contact:

Alan N. Moshell, M.D.
Skin Diseases Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 496-7326

For fiscal and administrative matters, contact:

Diane M. Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407-A
Bethesda, MD 20892
Telephone: (301) 496-7495

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under authorization of the Public Health Service Act, Title III, Section 301 (c) (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.